Impact of Multi-lumen Infusion Devices on the Occurrence of Physical Drug Incompatibilities: A Controlled in Vitro Study

Materials and Methods Two infusion devices were studied: 1) a standard set with six-gang-manifolds and its extension line and 2) a multi-lumen infusion access device with nine lumens (Edelvass-Multiline, Doran International, France). Six drugs were selected: three basic drugs (furosemide, pantoprazole and amoxicillin/clavulanic acid) and three acid drugs (amiodarone, dobutamine and midazolam). Two, four or six drugs and an infusion vehicle (saline, Ringer’s or 5% glucose) were infused simultaneously. The infusion rate of the vehicle was initially set at 100 mL/h and decreased stepwise by 10 mL/h until precipitate formation occurred. Physical incompatibility was assessed by visual inspection and sub-visible particle count test as defined by the European Pharmacopeia according to the European Pharmacopoeia. The lowest value of the vehicle infusion rate that satisfied the European Pharmacopeia according to the European Pharmacopoeia activity from the information provided by the Agencia Española de Medicamentos y Productos Sanitarios and the European activity from EU Clinical Trials Registers (European Medicines Agency website).

Results 782 protocols were evaluated (average 71 protocols/year).

Conclusions The CEIC workload was maintained, even increased, but because of OSs and unfunded research. The crisis marked a turning point; funded studies decreased and OSs increased. At the moment there are no noteworthy changes in Spanish or European CT activity.

Implementation of a Protocol for Selection of Biomedical Therapies in Rheumatology

Materials and Methods CEIC Minutes from a 500-bed university hospital were reviewed from 2000 to 2011, obtaining information from clinical trials (CTs) and observational studies (OS).

The financing of CTs was classified: 1) CTs promoted by the pharmaceutical industry, 2) by scientific societies with industry support, 3) by scientific societies with government support and 4) unfunded CTs. We compared two periods: pre-crisis (2000–2007) and crisis (2008–2011).

National scientific activity was obtained from a secondary data source from the information provided by the Agencia Española de Medicamentos y Productos Sanitarios and the European activity from EU Clinical Trials Registers (European Medicines Agency website).

Data analysis used conventional descriptive statistics.

Results 782 protocols were evaluated (average 71 protocols/year).

Conclusions There was an annual average decrease of 13 CT in groups 1 and 2, compared with the period 2000–2007 (95% CI: 4–22 CT).

Regarding the OSs, there was an annual average increase of 36 OSs during the second period (95% CI: 24–49 OS). There were no statistical differences between the two periods for groups 3 and 4.

The total number of protocols increased by an average of 25 projects/year during the second period compared to the first (95% CI: 8–40 projects).

There were 2340 CTs in Spain during the first period and 3096 during the second period (p = ns). CTs in Europe were 7,908 and 10,632 respectively (p = ns).

Conclusions The CEIC workload was maintained, even increased, but because of OSs and unfunded research. The crisis marked a turning point; funded studies decreased and OSs increased.

At the moment there are no noteworthy changes in Spanish or European CT activity.

Implementation of a Protocol for Selection of Biomedical Therapies in Rheumatology

Abstract OHP-047 Table 1

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of CTs</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>407</td>
<td>52</td>
</tr>
<tr>
<td>Group 2</td>
<td>53</td>
<td>7</td>
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<tr>
<td>Group 3</td>
<td>32</td>
<td>4</td>
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<tr>
<td>Group 4</td>
<td>93</td>
<td>12</td>
</tr>
<tr>
<td>OS</td>
<td>197</td>
<td>25</td>
</tr>
</tbody>
</table>

OHP-048 Impact of the Economic Crisis on Biomedical Research: Analysis of the Work of a Clinical Research Ethics Committee

Materials and Methods We analysed patients who had started treatment with BT or been switched from a previous biological treatment, since the implementation of the protocol (12/05/2011 to 29/02/2012). This document has different levels of decision based on both disease status and treatment effectiveness; RA: 1st level: infliximab or subcutaneous tumour necrosis factor inhibitor (anti-TNF) (etanercept or adalimumab); 2nd: tocilizumab or abatacept or rituximab; 3rd: golimumab or certolizumab pegol. SAPs: 1st level: infliximab or etanercept or adalimumab; 2nd: golimumab; 3rd: infliximab.

No conflict of interest.

IMPACT OF THE ECONOMIC CRISIS ON BIOMEDICAL RESEARCH: ANALYSIS OF THE WORK OF A CLINICAL RESEARCH ETHICS COMMITTEE

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No conflict of interest.

IMPACT OF MULTI-LUMEN INFUSION DEVICES ON THE OCCURRENCE OF PHYSICAL DRUG INCOMPATIBILITIES: A CONTROLLED IN VITRO STUDY

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No conflict of interest.